# SureTek Medical 510(k) Summary K052692

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| **Submitter** | SureTek Medical 25-B Maple Creek Circle Greenville, SC 29607 |
| **Contact** | Mike Sammon, Ph.D. 864-299-9743 |
| **Date** | 9/25/05 |
| **Product** | SureTek Reprocessed Electrosurgical Electrodes |
| **Classification** | Code: NUJ Regulation: 21 CFR 878.4400 Name: Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed. |

MAY 10 2006

**Predicate Devices**

| Manufacturer/Reprocessor | Device/System Tradenames | 510(k) |
|---|---|---|
| Arthrocare | ArthroWand*, PlasmaWand* | K033257, K033584 |
| Mitek | VAPR* | K963783 |
| Smith & Nephew | Vulcan*, Saphyre* | K050898 |
| Linvatec | UltrAblator, Lightwave* | K030720, K050923 |
| Arthrex | OPES* | K023986 |
| ValleyLab | Electrosurgical Device | K861112, K051627 |
| Vanguard Medical Concepts | Reprocessed Arthroscopic Wands | K043198 |
| Alliance Medical | Reprocessed Soft Tissue Ablators | K012631 |

**Device Description and Technological Features**

Devices are monopolar and bipolar electrosurgical electrodes designed for ablation, resection and coagulation of soft tissue. Instruments consist of one or more distal electrodes, an insulated shaft, and a proximal handle with electrical connections to a compatible electrosurgical unit. Monopolar instruments require concurrent use of a compatible return electrode. Models have varying electrode configurations and tip angles. Some models are equipped with suction tubing for continuous cooling of the ablation site and aspiration of fluids/debris during use. Reprocessed electrodes have equivalent technological characteristics as the predicate devices, i.e. device design, dimensions, energy delivery and system compatibility are unchanged during reprocessing. Device materials are identical with the exception of shaft insulation, which may be replaced with a comparable heat shrink material.

**Intended Use**

SureTek Reprocessed Electrosurgical Electrodes are intended for use during general, arthroscopic and endoscopic surgery for RF ablation, resection or coagulation of soft tissue and hemostasis of blood vessels.

**Testing and Standards**

- Simulated-use testing of instruments following maximum number of use and reprocessing cycles found their performance to be substantially equivalent to new, unused devices.
- Product insulation conforms to the relevant safety requirements of ANSI/AAMI HF18 *Electrosurgical Devices.*
- SureTek cleaning process is validated to be effective for decontamination of grossly contaminated instruments under worst case operational conditions.
- Product packaging conforms to all relevant requirements of ISO 11607 *Packaging for terminally sterilized medical devices*, with performance qualifications tested according to EN868-1 and ASTM F88-00, F2906-04, D4169-04a and F1980-02.
- Product sterility and process validation conform to the relevant requirements of ISO 11135 *Medical Devices – Validation and routine control of ethylene oxide sterilization.*
- Products conform to the relevant requirements of ISO 10993 *Biological Evaluation of Medical Devices* for ethylene oxide residuals and biocompatibility of device materials

**Substantial Equivalence**

Product testing and comparisons of specifications demonstrate that SureTek Reprocessed Electrodes are substantially equivalent to their predicate devices with respect to device design, technological characteristics, intended use and performance, as well as product packaging, labeling, sterility and safety.

* Product tradenames are registered trademarks of their respective manufacturers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

SureTek Medical
c/o Mike Sammon, BME, Ph.D.
CEO/President
25-B Maple Creek Circle
Greenville, South Carolina 29607

Re: K052692
Trade/Device Name: SureTek Reprocessed Electrosurgical Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: April 1, 2006
Received: April 5, 2006

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K052692

Device Name: SureTek Reprocessed Electrosurgical Electrodes

Indications for Use:

SureTek Reprocessed Electrosurgical Electrodes are intended for use during general, arthroscopic and endoscopic surgery for RF ablation, resection or coagulation of soft tissue and hemostasis of blood vessels.

Prescription Use — X — AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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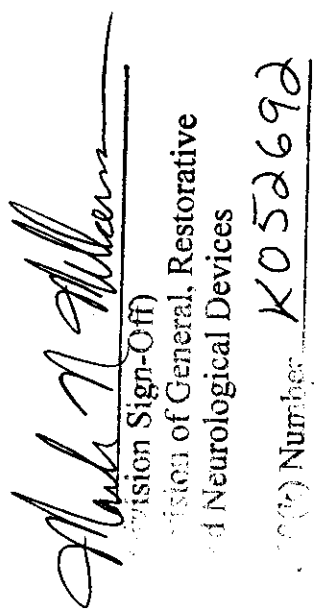
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K052692

SureTek Medical
Reprocessed Electrosurgical Electrodes found to be substantially equivalent:

| | | |
|---|---|---|
| Arthrex | OPES Ablator, Small Joint 45° | 2.5mm |
| Arthrex | OPES Ablator, Small Joint 30° | 2.5mm |
| Arthrex | OPES Ablator, 30° | 3.0mm |
| Arthrex | OPES Ablator, 60° | 3.0mm |
| Arthrex | OPES Ablator, 90° | 3.0mm |
| Arthrex | OPES Aspirating Ablator, 60° | 3.0mm |
| Arthrex | OPES Aspirating Ablator, 90° | 3.0mm |
| Arthrex | OPES Ablator, 90° | 4.0mm |
| Arthrex | OPES Aspirating Ablator, 90° | 4.0mm |
| ArthroCare | Bevel Arthrowand, 25° | 2.3mm, Black, Short 9cm |
| ArthroCare | Bevel Arthrowand, 35° | 2.3mm, Black, Short 9cm |
| ArthroCare | Bevel ArthroWand, 30° | 3.0mm, Black |
| ArthroCare | Bevel ArthroWand, 45° | 3.0mm, Black |
| ArthroCare | Bevel Arthrowand, 60° | 3.0mm, Black |
| ArthroCare | Dome 30 Arthrowand, 30° | 2.5mm, Black |
| ArthroCare | Dome 60 Arthrowand, 60° | 2.5mm, Black |
| ArthroCare | Dome 60 Arthrowand, 60° | 3.0mm, Black |
| ArthroCare | Eliminator ArthroWand, 90° | 4.5mm, Beige |
| ArthroCare | Eliminator ArthroWand, 90° | 4.5mm, Gray w/Cable |
| ArthroCare | Saber ArthroWand, 30° | 3.0mm, Beige |
| ArthroCare | Saber ArthroWand, 30° | 3.0mm, Gray w/Cable |
| ArthroCare | Saber ArthroWand, Straight | 3.5mm, Beige |
| ArthroCare | Covac 50 ArthroWand, 50° | 3.0mm, Beige, w/Suction |
| ArthroCare | CoVac 50 ArthroWand, 50° | 3.0mm, Gray w/Cable, w/Suction |
| ArthroCare | Covac 70 ArthroWand, 70° | 3.0mm, Beige, w/Suction |
| ArthroCare | TurboVac 90 Arthrowand, 90° | 3.5mm, Beige |
| ArthroCare | TurboVac 90 Arthrowand, 90° | 3.5mm, Gray w/Cable, w/Suction |
| ArthroCare | TurboVac HP Arthrowand, 90° | 3.5mm, High Profile, w/Suction |
| ArthroCare | Super TurboVac Arthrowand, 90° | 3.5mm, w/Cable, w/Suction |
| ArthroCare | Evac T&A PlasmaWand | 4.5mm, Blue, Coblator II |
| ArthroCare | Evac T&A PlasmaWand | 4.5mm, Blue w/Cable, Coblator II |
| Linvatec | Lightwave Ablator, 90° | 3.2mm, w/Cable |
| Linvatec | UltrAblator, Standard, 0° | 2.5mm |
| Linvatec | UltrAblator, Standard, 30° | 2.5mm |
| Linvatec | UltrAblator, Standard, 90° | 2.5mm |
| Linvatec | UltrAblator, Standard, 0° | 2.5mm |
| Linvatec | UltrAblator, Standard, 30° | 2.5mm |
| Linvatec | UltrAblator, Standard, 90° | 3.2mm |
| Linvatec | UltrAblator, Standard, 30° | 3.2mm |
| Linvatec | UltrAblator, Standard, 90° | 3.2mm |
| Linvatec | UltrAblator, 3-Rib, 30° | 3.2mm |
| Linvatec | UltrAblator, 3-Rib, 90° | 3.2mm |
| Linvatec | UltrAblator, 3-Rib, 30° | 3.2mm |
| Mitek | VAPR End Effect Electrode | 2.3mm |
| Mitek | VAPR End Effect Electrode | 3.5mm |
| Mitek | VAPR End Effect Electrode | 3.5mm, Angled 21° |
| Mitek | VAPR Side Effect Electrode | 2.3mm, 8.5cm |
| Mitek | VAPR Side Effect Electrode | 2.3mm |
| Mitek | VAPR Side Effect Electrode | 3.5mm |
| Mitek | VAPR Side Effect Electrode | 3.5mm, Angled 21° |
| Mitek | VAPR Hook Electrode 90° | 3.5mm |
| Mitek | VAPR Suction Electrode, 90° | 3.5mm |



SureTek Medical
Reprocessed Electrosurgical Electrodes found to be substantially equivalent:

| | | |
|---|---|---|
| Smith & Nephew | Ablator Probe Monopolar, 30° | 3.5mm, Black/Gray w/Cable |
| Smith & Nephew | Ablator Probe Monopolar, 60° | 3.5mm, Black/Gray w/Cable |
| Smith & Nephew | Ablator Probe Monopolar, 60° | 2.0mm, Black/Gray |
| Smith & Nephew | Ablator Probe Monopolar, 90° | 3.5mm, Black/Gray w/Cable |
| Smith & Nephew | Ablator Probe Monopolar, 90°, Hi Profile | 4.0mm, Black/Gray |
| Smith & Nephew | Ablator Probe Monopolar, 60° | 2.0mm, Black/Gray w/Suction |
| Smith & Nephew | Ablator Probe Monopolar, 60° | 3.5mm, Black/Gray w/Suction |
| Smith & Nephew | Ablator Probe Monopolar, 90° | 3.5mm, Black/Gray w/Suction |
| Smith & Nephew | Ablator Probe Monopolar, 90°, Hi Profile | 4.0mm, Black/Gray w/Suction |
| Smith & Nephew | Ablator Probe Monopolar, 90° | 2.0mm, Black/Gray w/Suction |
| Smith & Nephew | Ligament Chisel Monopolar | 3.5mm, Blue/Gray w/Cable, Angled |
| Smith & Nephew | Ligament Chisel Monopolar | 2.0mm, Blue/Gray w/Cable, Angled |
| Smith & Nephew | Ligament Chisel Monopolar | 3.5mm, Blue/Gray w/Cable, Curved |
| Smith & Nephew | Ligament Chisel Monopolar | 2.0mm, Blue/Gray w/Cable, Curved |
| Smith & Nephew | Ligament Chisel Monopolar | 3.5mm, Blue/Gray w/Cable, Hook |
| Smith & Nephew | Ligament Chisel Monopolar | 2.0mm, Blue/Gray w/Cable, Hook |
| Smith & Nephew | Ligament Chisel Monopolar | 3.5mm, Blue/Gray w/Cable, Straight |
| Smith & Nephew | Saphyre Bipolar Ablation Probe, 60° | 3.5mm, Gray |
| Smith & Nephew | Saphyre Bipolar Ablation Probe, 90° | 3.5mm, Gray |
| Smith & Nephew | Saphyre Bipolar Ablation Probe, 90° | 4.0mm, Gray, High Profile |
| Smith & Nephew | Saphyre II Bipolar Ablation Probe, 60° | 3.5mm, Gray w/Cable/Suction |
| Smith & Nephew | Saphyre II Bipolar Ablation Probe, 90° | 3.5mm, Gray w/Cable/Suction |
| Smith & Nephew | Saphyre II Bipolar Ablation Probe, 90° | 4.0mm, w/Cable/Suction, High Profile |
| ValleyLab | 3.0mm Blade Electrode | Rocker Switch, 10' Cable |
| ValleyLab | 3.0mm Blade Electrode | Pushbutton Switch, 10' Cable |

Division Sign-Off)
Division of General, Restorative
and Neurological Devices
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